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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,118	02/09/2006	Nicolas Beaudet	1912-0316PUS1	1706

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EXAMINER

SCHMIDTMANN, BAHAR

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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09/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/537,118	Applicant(s) BEAUDET ET AL.	
	Examiner BAHAR SCHMIDTMANN	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 7-28 and 31-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,29,30 and 40 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03 June 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/CA03/01899, filed 04 December 2003, which claims priority as a continuation-in-part under 35 U.S.C. §119(e) to US Provisional Application 60/430690, filed 04 December 2002.

The preliminary amendments filed 29 July 2009 is acknowledged. Claims 1-40 are pending in the current application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-30 and new claim 40 in the reply filed on 29 July 2009 is acknowledged. The traversal is on the ground(s) that the reference cited does not destroy novelty or non-obviousness. The examiner has found this persuasive because Kachlany et al. does not teach an exopolysaccharide/active agent composition.

However, the examiner would like to cite Pankaj (WO/2000/037051, cited in PTO-892). Pankaj teaches a micellar pharmaceutical composition comprising a pharmaceutical agent, wherein the micelle forming compounds include hyaluronic acid (abstract). As discussed below hyaluronic acid is an extracellular polysaccharide (evidenced by Biology Online Dictionary).

Applicant has argued that the reference cited does not teach a method of producing the delivery system. However, the technical feature among Groups I-III is not a method for making the delivery system, but rather the delivery system itself. As cited

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above, Pankaj teaches the common technical feature, i.e. an exopolysaccharide micelle formulated with an active agent.

Applicant has also argued since no unity rejection issued during the PCT International Phase, a rejection under PCT Rule 13.1 and 13.2 is improper. The examiner has not found this persuasive because restriction practices are optional, and determined on a case by case basis. See MPEP 802 and 35 U.S.C. 121.

The requirement is still deemed proper and is therefore made FINAL.

Claims 31-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, and claims 7-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 29 July 2009.

Information Disclosure Statement

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In

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addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

The images lack a measurement scale for the size of the particles.

Claim Objections

Claims 1 and 30 are objected to because of the following informalities: The recitation of "ofexopolysaccharide" could be corrected to recite "of exopolysaccharide" in claim 1. The recitation of "animmunomodulating" could be corrected to recite "an immunomodulating". Appropriate correction is required.

Claim 3 is objected to because of the following informalities: The scientific species names should be in italics.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "an immunomodulating amount of the delivery system" in claim 30 renders the claim herein indefinite. The specification does not define an immunomodulating amount. The specification does provide various experimental results on the effects of varying concentrations of exopolysaccharide on various cells (see p. 15-23, Tables 5-14). One of ordinary skill in the art would not know which concentration is readable on "immunomodulating amount". For purposes of examination, the examiner has interpreted this to be any amount greater than 0% by weight of said delivery system.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 29-30 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (WO/2000/041730, cited in PTO-892) as evidenced by Biology Online Dictionary (cited in PTO-892).

Brown discloses a method of co-administering an anti-neoplastic agent with hyaluronan to enhance the efficacy towards killing cancer cells (abstract). Brown teaches co-administering the active agent paclitaxel (a species of taxanes) to a patient in need of such treatment (claims 1-12, more specifically claims 2 and 10). Brown also discloses administration of hyaluronic acid/paclitaxel in a pharmaceutically acceptable carrier, i.e. ethanol and Cremophor EL and injection grade sodium chloride (p.28 lines 28-31 and p.29 lines 25-35), thus meeting the limitations of instant claims 29 and 30. Brown discloses hyaluronan forms a core for containing said active molecule (figure 1), meeting limitations of a micelle as defined in instant claim 1.

Biology Online Dictionary provides evidence that hyaluronic acid is a polysaccharide found in the extracellular matrix. Therefore, hyaluronic acid is inherently an exopolysaccharide.

It should be noted that the recitation of "immunomodulator composition" in claim 30 is an intended use and does not have patentable weight. See MPEP 2111.02.

Thus, the disclosure of Brown anticipates claims 1, 4-6, 29-30 and 40.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown as evidenced by Chong et al. (*Appl. Microbiol. Biotechnol.* cited in PTO-892).

Brown discloses as discussed above. Brown does not expressly disclose exopolysaccharide produced by lactic acid bacteria (instant claim 2).

Chong et al. discloses the production of hyaluronic acid via a microbial fermentation process (abstract). Chong et al. discloses hyaluronic acid is synthesized from pathogenic Lancefield group A and C streptococci (p.343, second column, second paragraph). Chong et al. discloses streptococci as lactic acid bacteria (p.346, second column). Therefore, Brown meets the structural limitation of the exopolysaccharide of instant claim 2.

Thus, the disclosure of Brown as evidenced by Chong et al. anticipates claims 1-2.

Conclusion

Claims 1-2, 4-6, 29-30 and 40 are rejected. Claim 3 is objected to for depending on a rejected claim and for minor informalities.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number is 571-270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Shaojia Anna Jiang/
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